health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Dr Maysseb Masenya
Cipla Medpro South Africa (Pty) Ltd
1474 South Road
Mobeni
DURBAN
4060

Dear Dr Masenya

Section 21 Authorization for Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial 2mL

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21authorisation must be accounted for.

9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent over stocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **12 December 2024**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC	12 300
FS	7 300
GP	35 400
KZN	34 400
LP	20 000
MP	12 800
NC	2 000
NW	8 300
WC	17 500
Total	**150 000**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 19/6/2024

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Section 21 Response Letter

6/12/2024 8:19 AM

Khadija Jamaloodien

National Department of Health
Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965):

Your application dated **6/11/2024 2:56 PM** refers

- ***A. STATUS: Approved***
- ***B. APPLICANT: Khadija Jamaloodien***
- ***C. IMPORTING COMPANY: Cipla Medpro Manufacturing (Pty) Ltd***
- ***D. PATIENT/(S):***
- ***E. UNREGISTERED MEDICINES:***

  GENERIC NAME: Poliomyelitis Vaccine Oral Bivalent Type 1 & 3

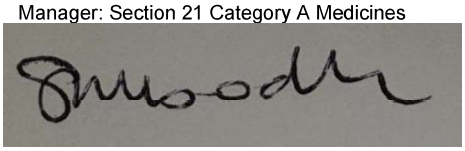
  TRADE NAME: Poliomyelitis Vaccine (Oral)
- ***F. QUANTITY: Poliomyelitis Vaccine Oral Bivalent Type 1 & 3 x 150 000 2mL vials***
- ***G. LETTER NUMBER: B-28081***

Section 21 authorization letters are valid for a period of six months from the letter date, unless otherwise specified.

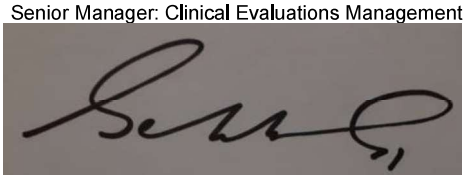
Comments:

Yours faithfully,

Dr S Munbodh
Manager: Section 21 Category A Medicines



T Sehloho
Senior Manager: Clinical Evaluations Management



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REQUEST FOR QUOTATION FORM

- **Instruction to complete this Request for Quotation (RFQ)**
  PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
  PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
  THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- **THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL		SECTION 21	X	**S21RFQ133**
QUOTE ENQUIRY DATE	**06/05/2024**	QUOTE CLOSING DATE			**15/05/2024**
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE *(SCM Practitioner to Specify if applicable)*					

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo		
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za		
PHONE No.	**012 395 9539**	FAX No.	**N/A**

PRODUCT INFORMATION

DESCRIPTION PER MPC	**POLIOMYLITIS ORAL BIVALENT VACCINE 20 DOSE 3ML (Bivalent Oral Polio Vaccine 3mL 20 Dropper)**		
TRADE DESCRIPTION	Poliomyelitis Vaccine (Oral) Bivalent type1 and 3 – 20 Dose Vial (With VVM) with Droppers		
UNIT OF MEASURE	**1's**	PACK or BOX (*SIZE/ QUANTITY*)	50 Vials per shipper/box
QUANTITY REQUIRED	**150000 Vials**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

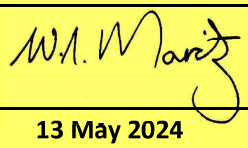
SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Cipla Medpro Manufacturing (Pty) Ltd			
SUPPLIER NUMBER	MAAA1168386			
SECURITY CODE	2DED438B-80A9-457F-89CA-E570DF24BCD6			
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	**Willem Maritz**		
	PHONE	**0113159150**	FAX	
	MOBILE	*0828874926*		
	E-MAIL	**willem.maritz@cipla.com**		
CONTACT PERSON 2	NAME	**Dr Pieta Serfontein**		

	PHONE	
	MOBILE	*0836033462*
	E-MAIL	**Pieta.serfontein@cipla.com**

QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R95.74	TOTAL PRICE (INCL. DELIVERY & VAT)	R14361000.00
VOLUMES AVAILABLE – 14DAYS	30 000		
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	120 000		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	Price Validity till 31/12/2024 subject to successful S21 Application		
NORMAL LEAD/DELIVERY TIME	First stock of 30 000 available within 2 to 4 weeks, balance 8 to 12 weeks		

DEVIATION TO SPECIFICATION
COMMENTS: Shipper of 50 vials with Droppers packed separately in shipper carton. Please order in multiples of 50 (one shipper carton)

DECLARATION BY SUPPLIER	
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.	
NAME	**Willem Maritz**
CAPACITY	**Director-State Business**
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*	
DATE	**13 May 2024**

Please submit quotations to Section21Quotes@health.gov.za

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Central Supplier Database Summary Report (CSD)
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)

All of the above is required to expedite the process in considering the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

NB:

- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ.
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices must please be submitted in two decimals.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

Monday, 13 May 2024

To: National Department of Health

CC: Head of Pharmaceutical Services
Depot Managers
District Managers
Drug Controllers

From: Cipla Medpro South Africa (Pty) Ltd
Tel: 021 914 0520

Date: 13 May 2024

Re: RFQ for Section 21 Quotation: S21RFQ131 Bivalent Oral Polio Vaccine 3mL 20 Dropper Vial

Please find a Quote for.

Poliomyelitis Vaccine (Oral) Bivalent type 1 and 3 – 20 Dose Vial (With VVM) with Droppers – R95.74 including VAT at 15%, per vial.

QUOTE VALID UNTIL 31/12/2024.

Price is firm for validity period.
Current available stock is 30 000 vials ready in India and can be imported within 2 to 4 weeks. Balance available within 8 to 12 weeks. Shelf life is normally 24 months, stock offered will have at least 50% or better shelf life remaining at time of delivery.

Packaging is Serum Institute of India Pvt Ltd, standard UNICEF packaging.

Company Name: Cipla Medpro Manufacturing (Pty) Ltd
Supplier number: MAAA1168386
Security code: 2DED438B-80A9-457F-89CA-E570DF24BCD6
Supplier Code (NDoH): VS2P5

Cipla Medpro Manufacturing (Pty) Ltd reserves the right to recall the validity of this quote if there are any errors and/or omissions in this quote as well as to decline additional orders if it is beyond the company's manufacturing capabilities or will cause unrealistic lead times upon consultation with the procuring authorities and manufacturer.

Regards

For and on behalf of

Willem Maritz
Director - State Business.
Cell: 082 887 4926
e-mail:willem.maritz@cipla.com
E&OE
Cipla Medpro Manufacturing (Pty) Ltd

SERUM INSTITUTE OF INDIA PVT. LTD.
Cyrus Poonawalla Group

Corporate Plant Format

Title	Artwork Format		
Format No.	2002-0001-F0003-000		
Effective Date	09/11/2020	**Page No.**	1 of 2

Poliomyelitis Vaccine (oral)

Bivalent type 1 and 3

DESCRIPTION
Poliomyelitis Vaccine (oral) bivalent type 1 and 3 (bOPV) is a vaccine containing suspensions of types 1 and 3 live attenuated poliovirus (Sabin strain). The attenuated virus particles in bOPV are harvested from monkey kidney cell cultures. 1 Molar Magnesium chloride as a stabilizer. bOPV contains 15 mcg of neomycin. It also contains traces of Erythromycin and Kanamycin. bOPV also contains polysorbate 80. bOPV is administered multiple times to ensure immunity to all two types of poliovirus. Polio vaccine is manufactured from the bulk imported from PT BIO FARMA (Persero), Indonesia. The vaccine meets the requirements of WHO when tested by the methods outlined in current WHO, TRS.

COMPOSITION
Each dose of 2 drops (0.1 ml) contains
Polio Virus (Sabin), grown on
Primary Monkey Kidney culture
Type - I ≥ $10^{6.0}$ $CCID_{50}$
Type - III ≥ $10^{5.8}$ $CCID_{50}$
Neomycin 15 mcg
Stabilizer : 1 M $MgCl2$

INDICATIONS
Bivalent OPV (Type 1 and 3) is indicated for active immunization against Type 1 and 3 polioviruses.

CONTRAINDICATIONS
No adverse effects are produced by giving bOPV to a sick child. In case of diarrhoea or vomiting (including gastro-intestinal infection), the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

IMMUNE DEFICIENCY
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with bOPV according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

PRECAUTIONS
The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be evaluated.

ADVERSE REACTIONS
In the vast majority of cases there are no side effects. Very rarely, there may be vaccine associated paralysis (one case per one million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine associated paralytic poliomyelitis.

DOSAGE AND ADMINISTRATION
Bivalent OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi dose vial by dropper. For older children it may be preferred to avoid the possible bitter taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi dose dropper with saliva of the vaccinee. Overdose, if any, will not result in ill-effect.
Once opened, multi-dose vials should be kept between +2° C and +8° C. Multi-dose vials of bOPV from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07:

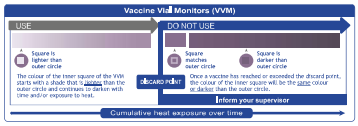
- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;
- The expiry date of the vaccine has not passed;
- The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

IMMUNIZATION SCHEDULE
Bivalent OPV (type 1 and 3) is indicated for routine and supplementary immunization activities (SIAs) against type 1 and 3 poliovirus in all age groups. The use of this vaccine should be in accordance with official recommendations. bOPV can be given safely and effectively at the same time as DPV, measles, rubella, mumps, DTP, DT, TT, Td, BCG, hepatitis B, Haemophilus influenzae type b, yellow fever vaccine and Vitamin A supplementation.

STORAGE
Vaccine is potent if stored at not higher than -20° C until the expiry date indicated on the vial. It can be stored for upto six months between -2° C and +8° C.
The vaccine may present a colour varying from light yellow to dark pink due to a slight variation of pH, however this does not affect the quality of vaccine.

PRESENTATION
1 ml = 10 doses vial
2 ml = 20 doses vial

THE VACCINE VIAL MONITOR (VVM) (Optional)



Vaccine Vial Monitors (VVMs) are part of the label on Poliomyelitis Vaccine (oral) bivalent type 1 and 3 supplied through Serum Institute of India Pvt. Ltd. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.
The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the outer circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the outer circle or of a darker colour than the outer circle, then the vial should be discarded.

INSTRUCTIONS FOR USE:
The vial must first be shaken gently to avoid foaming, but sufficiently to obtain a homogenous mixture of the contents. Remove the flip top tear down seal, the rubber cap and fix the pre-sterilized plastic dropper supplied along with the vial. Remove the flip top from the aluminium part of seal along the direction of the indication on the flip. Pull the seal from the stoppered vial. Hold the vial inverted in tilted position and gently squeeze the plastic dropper to expel the vaccine drop-by-drop.

Directions for use of dropper during vaccine delivery

Hold the vial in tilted position during vaccine delivery into the mouth

Do not hold the vial horizontally for vaccine delivery into the mouth

Do not hold the vial vertically for vaccine delivery into the mouth

Directions for the dropper
1. Use specific droppers supplied by Serum Institute of India Pvt. Ltd.
2. Dropper should be discarded with the vaccine vial as re-use of droppers from one vial to another may lead to crack and leakage.
3. Always hold the vial in tilted position (ref. figure 1) for vaccine delivery.
4. Press the dropper gently just above the delivery nozzle with soft part of the fingers avoiding nail contact.
5. Bring vial along with dropper to upright position after delivery of each dose.
6. Put the nozzle cover back on the dropper when there is some time elapsed between two consecutive vaccine deliveries.

Revision date: 06/2021

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411028, INDIA
Protection from birth onwards

20011253/4

Vacuna Antipoliomielítica (oral)

Bivalente tipo 1 y 3

DESCRIPCIÓN
La vacuna antipoliomielítica (oral) de tipo bivalente 1 y 3 (bOPV) es una vacuna que contiene las suspensiones de los tipos 1 y 3 poliovirus vivo, atenuado (cepa Sabin). Las partículas del virus atenuado en la bOPV se cosechan de los cultivos de las células del riñón de mono. Se utiliza el Cloruro de Magnesio de 1 Molar como estabilizador. La bOPV contiene 15 mcg de neomicina. También contiene trazas de eritromicina y kanamicina. La bOPV también contiene polisorbato 80. La bOPV se administra múltiples veces para asegurar la inmunidad a los dos tipos de virus de polio. La vacuna contra la polio se fabrica con el producto a granel importado de PT BIO FARMA (Persero), Indonesia. La vacuna cumple con los requisitos de la OMS cuando se la comprueba según los métodos descritos en la OMS TRS vigente.

COMPOSICIÓN
Cada dosis de 2 gotas (0,1 ml) contiene
Virus de polio (Sabin) crecido en el
cultivo primario de riñón de mono
Tipo - I ≥ $10^{6.0}$ $CCID_{50}$
Tipo - III ≥ $10^{5.8}$ $CCID_{50}$
Neomicina 15 mcg
Estabilizador : 1 M $MgCl2$

INDICACIONES
OPV Bivalente (tipo 1 y 3) está indicada para inmunización activa contra los poliovirus tipo 1 y tipo 3.

CONTRAINDICACIONES
No se producen efectos adversos por la administración de la bOPV en un niño enfermo. En el caso de la diarrea o vómitos (incluyendo la infección gastro-intestinal), la dosis recibida no se incluirá como parte del esquema de inmunización y debe repetirse después de la recuperación.

INMUNODEFICIENCIA
Los individuos infectados con el Virus de la Inmunodeficiencia Humana (VIH), sean sintomáticos o asintomáticos, deben inmunizarse con la bOPV, de conformidad con los esquemas estándares. Sin embargo la vacuna está contraindicada en personas con la enfermedad primaria de inmunodeficiencia o una respuesta inmune suprimida por causa de la medicación, leucemia, linfoma o la malignidad generalizada.

PRECAUCIONES
La posibilidad de reacciones alérgicas en individuos sensibles a los componentes de la vacuna debe ser evaluada.

REACCIONES ADVERSAS
En la gran mayoría de los casos no existen efectos secundarios. Muy raramente, puede ocurrir la parálisis asociada con la vacuna (en un caso por un millón de dosis administradas). Las personas en estrecho contacto con un niño recién vacunado pueden muy raramente correr el riesgo de la poliomielitis paralítica asociada con la vacuna.

POSOLOGÍA Y ADMINISTRACIÓN
La OPV Bivalente debe ser administrada por vía oral. Se administran dos gotas del frasco multidosis directamente en la boca, utilizando el gotero. Para niños mayores tal vez sea preferible mezclar las gotas en un terrón de azúcar o en un jarabe para evitar el posible sabor amargo. Se debe tomar el cuidado de no contaminar un gotero de múltiples dosis con la saliva del vacunado. Si ocurre la sobredosificación, no resultará en ningún efecto nocivo.
Una vez abiertos, los frascos multidosis deben guardarse entre -2° C y +8° C. Los frascos multidosis de la bOPV, de los cuales se hayan removido una o más dosis de la vacuna durante una sesión de inmunización pueden ser usados en las sesiones de inmunización subsecuentes durante un máximo de 28 días, a condición de que todas las condiciones se cumplan (según descrito en la declaración de política de la OMS: Manejo de frascos de vacuna multi-dosis después de la apertura, OMS/IVB/14.07:

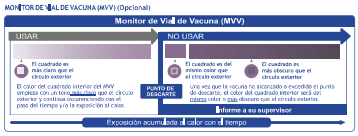
- La vacuna actualmente está precalificada por la OMS;
- La vacuna está aprobada para uso hasta 28 días después de abrir el frasco, según determinado por OMS;
- La fecha de caducidad de la vacuna no se haya pasado;
- El frasco de la vacuna ha sido y seguirá siendo, almacenados en temperaturas recomendadas por la OMS o el fabricante; además el sensor de control de vial de vacuna, hay, es visible en la etiqueta de la vacuna y no haya sobrepasado su punto de descarte, y la vacuna no haya sufrido daños por congelación.

ESQUEMA DE INMUNIZACIÓN
La OPV Bivalente (tipo 1 y 3) está indicada para las actividades de inmunización de rutina y complementarias (AVS) en contra del poliovirus tipo 1 y 3 en todos los grupos etarios. El uso de esta vacuna debe ser de acuerdo con las recomendaciones oficiales. La bOPV puede ser administrada segura y eficazmente simultáneamente con las vacunas de DPV, sarampión, rubeola, parotiditis, DTP, DT, TT, Td, BCG, Hepatitis B, Haemophilus influenzae tipo b, fiebre amarilla y suplementos de Vitamina A.

CONSERVACIÓN
La vacuna es potente si se conserva a no más de -20° C hasta la fecha de caducidad indicada en el frasco. Puede ser guardada por un máximo de seis meses entre +2° C y +8° C.
La vacuna puede presentar un color que varía de amarillo claro a rosa oscura debido a una ligera variación del pH, sin embargo esto no afecta la calidad de la vacuna.

PRESENTACIÓN
Frasco de 1 ml = 10 dosis
Frasco de 2 ml = 20 dosis

MONITOR DE VIAL DE VACUNA (MVV) (Opcional)



Los monitores de vial de vacuna (MVV) forman parte de la etiqueta de Vacuna Antipoliomielítica (oral) bivalente de tipo 1 y 3 suministrada por Serum Institute of India Pvt. Ltd. El punto colorido que aparece en la etiqueta del vial es un VVV. Es un punto sensible al tiempo y la temperatura que indica el calor acumulado al cual haya sido expuesto el frasco. Avisa al consumidor final cuando es probable que la exposición al calor haya podido degradar la vacuna fuera del nivel de aceptación.
La interpretación del MVV es sencilla. Enfocarse en el cuadrado central. Su color cambiará progresivamente. Si el color de este cuadrado es menos oscuro que el color del círculo exterior, la vacuna puede utilizarse. Una vez que el color del cuadrado central tenga el mismo color que el círculo exterior o se vuelva un color más oscuro que el color del círculo exterior, el frasco debe desecharse.

INSTRUCCIONES DE USO:
El vial debe ser agitado suavemente primero para evitar la formación de espuma, pero suficientemente para obtener una mezcla homogénea de los contenidos. Retirar el sello tipo flip-top, el tapón de goma y fijar el cuentagotas de plástico pre-esterilizado, suministrado junto con el vial. Retirar el tapón tipo flip-top de la parte del sello de aluminio en el sentido indicado en la tapa. Sostener el frasco invertido en una posición inclinada y apretar suavemente el gotero de plástico para expulsar la vacuna gota a gota.

La posición en que se debe sostener el gotero durante la administración de la vacuna

Sostener el frasco inclinado cuando administra la vacuna en la boca.

No sostenga el frasco horizontalmente para la administración de la vacuna en la boca.

No sostenga el frasco verticalmente para administrar la vacuna en la boca.

Instrucciones de uso para el gotero
1. Usar los goteros suministrados por el Serum Institute of India Pvt. Ltd.
2. El gotero debe ser descartado junto con el vial de la vacuna ya que la re-utilización de goteros entre frascos puede llevar a grietas y fugas.
3. Siempre sostener el frasco en la posición inclinada (referirse a la figura 1) para la administración de la vacuna.
4. Apretar el gotero suavemente, justo encima de la boquilla con la parte suave de los dedos evitando el contacto con las uñas.
5. Colocar el frasco junto con el gotero en una posición vertical después de la entrega de cada dosis.
6. Volver a colocar la cubierta de la boquilla en el gotero cuando transcurra un período de tiempo entre dos administraciones consecutivas de la vacuna.

Fecha de revisión: 06/2021

Fabricada por:
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411028, INDIA
Protección desde el nacimiento

Reason for issue: Text revised			Specification: To be printed on bible paper 40 gsm	
Customer: WHO/UNICEF/PAHO				
Product: **ORAL POLIO VACCINE**	**Bivalent**		Colour: C M Y K Pantone 376 C and 072 C	
Item Code number: 20011253/4		Specification No.:		Artwork made to: 100%
Supercedes Item Code: 20011253/3			Dimensions: 470 x 205 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name:E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Insert\WHO\OPV\Bivalent\OPV bivalent insert 3 lang- WHO.cdr Rev. on: 16.03.2021

SERUM INSTITUTE OF INDIA PVT. LTD.
Cyrus Poonawalla Group

Corporate Plant
Format

Title	Artwork Format		
Format No.	2002-0001-F0003-000		
Effective Date	09/11/2020	**Page No.**	2 of 2

Vaccin Poliomyélitique (oral)

Bivalent type 1 et 3

DESCRIPTION
Le Vaccin Poliomyélite (oral) bivalent de types 1 et 3 (bVPO) est un vaccin contenant des suspensions de types 1 et 3 du poliovirus vivant atténué (souche Sabin). Les particules virales atténuées dans le bVPO sont recultivées à partir des cultures cellulaires des reins de singe. 1 flacon de chlorure de magnésium en tant que stabilisant. Le bVPO contient 15 mcg de néomycine. Il contient aussi des traces de l'érythromycine et de la kanamycine. Le bVPO contient également du polysorbate 80. Le VPOb est administré à plusieurs reprises pour assurer l'immunité à tous les deux types de poliovirus. Le vaccin contre la polio est fabriqué à partir du virac fourni par PT BIO FARMA (Persero), en Indonésie. Le vaccin est conforme aux exigences de l'OMS lors de l'essai par les méthodes décrites dans la SRT actuelle de l'OMS.

COMPOSITION
Chaque dose de 2 gouttes (0,1 ml) contient
Virus de la poliomyélite (Sabin), cultivé
sur une culture primaire de reins de singe
Type - 1 ≥ $10^{6.0}$ $CCID_{50}$
Type - III ≥ $10^{5.8}$ $CCID_{50}$
Néomycine 15 mcg
Stabilisant : 1 M $MgCl2$

INDICATIONS
Le VPO bivalent (type 1 et 3) est indiqué dans l'immunisation active contre les polio-virus de types 1 et 3.

CONTRE-INDICATIONS
Aucun effet néfaste n'est produit en donnant le bVPO à un enfant malade. En cas de diarrhée ou de vomissements (y compris les infections gastro-intestinales), la dose reçue ne sera pas comptée dans le cadre du calendrier de vaccination et elle sera répétée après récupération.

IMMUNODÉFICIENCE
Les personnes infectées par le virus de l'immunodéficience humaine (VIH), asymptomatiques et symptomatiques, doivent être vaccinées avec le bVPO selon le calendrier standard.
Cependant, le vaccin est contre-indiqué chez ceux souffrant d'un déficit immunitaire primaire ou d'une réponse immunitaire supprimée due aux médicaments, à la leucémie, au lymphome ou à un cancer généralisé.

PRÉCAUTIONS
La possibilité de réactions allergiques chez les personnes sensibles aux composants du vaccin doit être évaluée.

EFFETS INDÉSIRABLES
Dans la grande majorité des cas, il n'y a pas d'effets secondaires. Très rarement, il peut y avoir une paralysie associée au vaccin (un cas par million de doses administrées). Les personnes en contact étroit avec un enfant récemment vacciné peuvent très rarement être à risque de la poliomyélite paralytique associée au vaccin.

POSOLOGIE ET ADMINISTRATION
Le VPO Bivalent doit être administré uniquement par voie orale. Deux gouttes sont administrées directement dans la bouche depuis un flacon à doses multiples par un compte-goutte. Pour les enfants plus âgés, il peut être préférable d'éviter le goût amer en plaçant d'abord les gouttes sur un morceau de sucre ou dans un sirop. Il faut prendre soin de ne pas contaminer le compte-gouttes à doses multiples avec la salive de la personne vaccinée. Un surdosage, le cas échéant, n'entraînera d'effets indésirables.
Une fois ouverts, les flacons à doses multiples doivent être conservés entre +2° C et +8° C. Les flacons à doses multiples du bVPO, d'où une ou plusieurs doses de vaccin ont été enlevées au cours d'une séance de vaccination, peuvent être utilisés dans des séances de vaccination subséquentes jusqu'à un maximum de 28 jours, pourvu que toutes les conditions suivantes soient remplies (telles que décrite dans la déclaration de politique de l'OMS:
Manipulation des flacons de vaccin multidoses entamés, DRAFT/8/14.07:

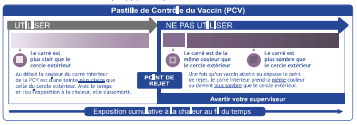
- Le vaccin est actuellement préqualifié par l'OMS;
- Son utilisation jusqu'à 28 jours après l'ouverture du flacon est homologuée, conformément à ce qui a été déterminé par l'OMS;
- La date de péremption du vaccin n'est pas dépassée;
- Le flacon de vaccin a été et continuera d'être conservé aux températures recommandées par l'OMS ou le fabricant; de plus, la pastille de contrôle du vaccin, s'il en est muni, est visible sur l'étiquette du vaccin et n'a pas dépassé le point limite d'utilisation, et le vaccin n'a pas été endommagé par le gel.

CALENDRIER DE VACCINATION
Le VPO bivalent (type 1 et 3) est indiqué pour les activités de vaccination systématique et supplémentaire (AVS) contre le type 1 et 3 du poliovirus dans tous les groupes d'âge. L'utilisation de ce vaccin doit être en conformité avec les recommandations officielles. Le bVPO peut être administré en toute sécurité et efficacement en même temps que le vaccin VPI, le vaccin contre la rougeole, la rubéole et les oreillons, les vaccins DTC, DT, AT, Td, BCG, les vaccins contre l'hépatite B, l'haemophilusinfluenzae de type b, la fièvre jaune et la supplémentation en vitamine A.

CONSERVATION
Le vaccin est efficace s'il est conservé à une température pas supérieure à +20° C jusqu'à la date de péremption indiquée sur le flacon. Il peut être conservé pendant un maximum de six mois entre +2° C et +8° C.
Le vaccin peut présenter une couleur variant du jaune pâle au rose foncé en raison d'une légère variation de pH, mais cecin'affecte pas la qualité du vaccin.

PRESENTATION
1 ml - flacon de 10 doses
2 ml - flacon de 20 doses

PASTILLE DE CONTRÔLE DU VACCIN (PCV) (Optionnel)



Les pastilles de contrôle du vaccin (PCV) font partie de l'étiquetage affiché sur le flacon du Vaccin Poliomyélitique (oral) de types 1 et 3 bivalent fourni par Serum Institute of India Pvt. Ltd. Le cercle de couleur qui apparaît sur l'étiquette est une PCV. Il s'agit d'un point sensible au temps écoulé et à la température et indique la chaleur cumulative à laquelle le flacon a été exposé. Cela avertit l'utilisateur final au cas où l'exposition à la chaleur aurait dégradé le vaccin au-delà d'un niveau acceptable.
L'interprétation de la PCV est facile. Il ne faut que se concentrer sur le carré intérieur. Sa couleur changera progressivement, tant que la couleur de carré est plus claire que celle du cercle extérieur, on peut utiliser le vaccin. Lorsque le carré central est de la même couleur que le cercle extérieur ou plus foncé que le cercle excterieur, on doit jeter le flacon.

MODE D'EMPLOI:
Le flacon doit d'abord être agité doucement pour éviter le moussage, mais suffisamment pour obtenir un mélange homogène du contenu. Retirez la fermeture à rabat en déchirant vers le bas. le bouchon de caoutchouc et fixezle compte-goutte en plastique pré- sterilisefourni avec le flacon. Enlevez le couvercle rabattable de la partie de joint d'écranchété en aluminium le long de la direction indiquée. Tirez le joint du flacon bouché. Tenez le flacon inversé en position inclinée et pressez doucement la pipette en plastiqiue pour expulser le vaccin goutte-à-goutte.

La position du compte-gouttes au cours de l'administration du vaccin

Tenez le flacon en position inclinée lors de l'administration du vaccin par voie orale.

Ne tenez pas le flacon en position horizontale lors de l'administration du vaccin par voie orale.

Ne tenez pas le flacon en position verticale lors de l'administration du vaccin par voie orale.

Instructions pour utiliser le compte-gouttes
1. Utilisez le compte-gouttes fourni par Serum Institute of India Pvt. Ltd.
2. Le compte-gouttes doit être jeté avec le flacon du vaccin car la réutilisation du compte-gouttes d'un flacon à l'autre peut entraîner des fissures et par conséquent une fuite.
3. Il faut toujours tenir le flacon en position inclinée (Réf. Figure 1) pour administrer le vaccin.
4. Appuyez sur le compte-gouttes doucement juste au-dessus de la base de distribution avec la partie tendre des doigts en évitant le contact avec l'ongle.
5. Remettez le flacon avec le compte-gouttes en position verticale après l'administration de chaque dose.
6. Rebouchez le compte-gouttes si du temps est écoulé entre deux administrations consécutives du vaccin.

Date de révision: 06/2021

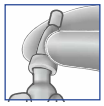
Fabriqué par :
SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411028, INDIA
Protection dès la naissance

Directions for fixing the dropper on the OPV vial
Instrucciones para fijar el gotero en el frasco
Itinéraire pour la fixation du compte-gouttes sur le flacon de VPO

Or / O / Oregón

1. Remove the flip top of the cap by applying upward pressure at the point marked "LIFT" or arrow 〜
Caution: Upward pressure has to be applied only at the marked point.
1. Quite la tapa 'flip-top' aplicando presión hacia arriba en el punto marcado "LIFT" o en la flecha 〜
Cuidado: La presión hacia arriba solo debe aplicarse en el punto marcado.
1. Retirez la capsule rabattable du capuchon en exerçant une pression vers le haut à l'endroit indiqué 'SOULEVEZ' ou sur la flèche 〜
Attention: La pression vers le haut doit être appliquée seulement au point marqué.

2. Once the flip top is detached, pull it over the edge of the seal and downward to the lower end of the vial mouth and rotate it counter clockwise in the direction of the arrow above the word "TEAR".
Similar procedure to be used for arrow marked seal.
2. Una vez retirada la tapa 'flip-top, empújala hacia el borde del sello y hacia abajo hasta la extremidad inferior de la boca del frasco y gírela en el sentido antihorario en la dirección de la flecha encima de la palabra "TEAR".
Procedimiento similar para ser utilizado para la flecha marcada con.
2. Une fois que la capsule rabattable est détachée, tirez sur le bord du joint et vers le bas à l'extrémité inférieure de la bouche du flacon et tournez-la dans le sens contraire des aiguilles dans le sens de la flèche au-dessus du mot "DECHIREZ" le mot.
Il faut utiliser la même procedure pour une fermeture marquée avec une flèche.



3. Remove the crimp cap completely. Rotating in the wrong direction will result in the flip top snapping off without removal of crimp cap.
3. Retire la tapa de aluminio completamente. Si se la gira en la dirección equivocada, la tapa tipo 'flip-top' romperá sin que sea retirada la tapa de aluminio.
3. Retirez le capuchon de sertissage complètement. Tourner dans le mauvais sens cassera la capsule rabattable sans qu'elle soit enlevée.

4. Remove the rubber stopper. Attach the dropper to the vial mouth.
4. Retire el tapón de goma. Coloque el gotero en la boca del frasco.
4. Retirez le bouchon en caoutchouc. Fixez le compte-gouttes à la bouche du flacon.

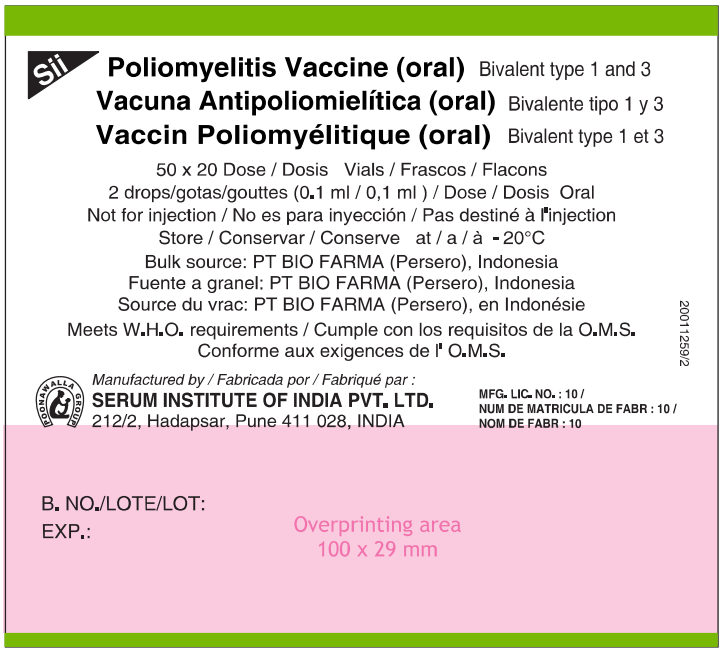
Reason for issue: Text revised			Specification: To be printed on bible paper 40 gsm	
Customer: WHO/UNICEF/PAHO				
Product: **ORAL POLIO VACCINE**	**Bivalent**		Colour: C M Y K Pantone 376 C and 072 C	
Item Code number: 20011253/4		Specification No.:	Artwork made to: 100%	
Supercedes Item Code: 20011253/3			Dimensions: 470 x 205 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name:E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Insert\WHO\OPV\Bivalent\OPV bivalent insert 3 lang- WHO.cdr Rev. on: 16.03.2021

SERUM INSTITUTE OF INDIA PVT. LTD.
Cyrus Poonawalla Group

Corporate Plant
Format

Title	Artwork Format		
Format No.	2002-0001-F0003-000		
Effective Date	09/11/2020	**Page No.**	1 of 1



Reason for issue: Increase in batch coding area for 2D code		Specification: Self Adhesive Label To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form.
Customer: Exports - WHO		
Product: **ORAL POLIO VACCINE - Bivalent** 2 ml -20 doses		Colour: Pantone 376 C and Black
Item Code number: 20011259/2	Specification No.:	Artwork made to: 100%
Supercedes Item Code: 20011259/1		Dimensions: 100 x 90 mm

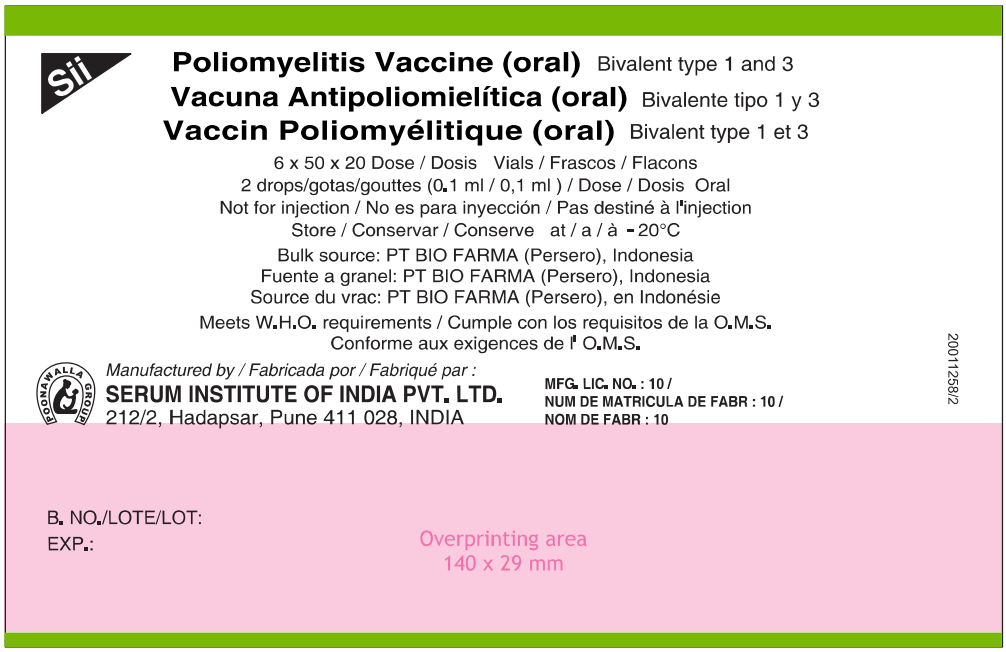
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name: E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Polio\Bivalent\OPV English Bivalent\OPV Bivalent.cdr Date: 09.08.2021

SERUM INSTITUTE OF INDIA PVT. LTD.
Cyrus Poonawalla Group

Corporate Plant
Format

Title	Artwork Format		
Format No.	2002-0001-F0003-000		
Effective Date	09/11/2020	**Page No.**	1 of 1



Reason for issue: Increase in batch coding area for 2D code		Specification: Self Adhesive Label To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form.
Customer: Exports - WHO		
Product: **ORAL POLIO VACCINE - Bivalent** 2 ml -20 doses		Colour: Pantone 376 C and Black
Item Code number: 20011258/2	Specification No.:	Artwork made to: 100%
Supercedes Item Code: 20011258/1		Dimensions: 140 x 90 mm

PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

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SERUM INSTITUTE OF INDIA PVT. LTD.

Poliomyelitis Vaccine (oral)

2 ml - 20 doses

Bivalent type 1 and 3

Each dose of 2 drops (0.1 ml) contains
Polio virus (Sabin), grown on
Primary Monkey Kidney culture
Type - I ⩾ $10^{6.0}$ $CCID_{50}$
Type - III ⩾ $10^{5.8}$ $CCID_{50}$
Neomycin 15 mcg Stabilizer : 1 M $MgCl_2$
1 dose = 2 drops, oral route Not for injection
Store at - 20°C SHAKE WELL BEFORE USE
Bulk source: PT BIO FARMA (Persero), Indonesia

20011264/3

HEATmarker ® VVM2

Meets W.H.O. requirements

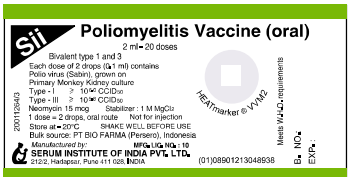
B. NO.:

EXP.:

Manufactured by: **MFG. LIC. NO. : 10**

SERUM INSTITUTE OF INDIA PVT. LTD.
212/2, Hadapsar, Pune 411 028, INDIA

(01)08901213048938



Reason for issue: Addition of "PVT." in Co. Name		Specification: Happa nylon block To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form.		
Customer: Exports - WHO				
Product: **ORAL POLIO VACCINE - Bivalent** 2 ml -20 doses		Colour: Pantone 376 C and Black		
Item Code number: 20011264/3	Specification No.:		Artwork made to: 100%	
Supercedes Item Code: 20011264/2		Dimensions: 48 x 24 mm		
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

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035 5205/8/F3